

### (19) World Intellectual Property Organization International Bureau





## (43) International Publication Date 9 June 2005 (09.06.2005)

PCT

# (10) International Publication Number WO 2005/051349 A3

(51) International Patent Classification7: 9/28, 31/55, A61P 25/20

A61K 9/20,

(21) International Application Number:

PCT/IB2004/003872

(22) International Filing Date:

24 November 2004 (24.11.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

964/CHE/2003

25 November 2003 (25.11.2003) TN 17 September 2004 (17.09.2004)

930/CHE/2004 (71) Applicant (for all designated States except US): AU-ROBINDO PHARMA LTD. [IN/IN]; Plot No.

Maitrivihar, Ameerpet, Hyderabad 500038 (IN).

(72) Inventors; and

- (75) Inventors/Applicants (for US only): ALURI, Phanindrudu [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). BABU, Justin [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). RAO, Shaik, Srinivasa [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN). GOGIA, Ashish [IN/IN]; Aurobindo Pharma Ltd., Plot No.2 Maitrivihar, Ameerpet, Hyderabad 500038 (IN).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

### Declaration under Rule 4.17:

of inventorship (Rule 4.17(iv)) for US only

#### Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 28 July 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS OF MIRTAZAPINE

(57) Abstract: The present invention relates to pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts. More particularly, the present invention relates to solid unit dosage forms of anhydrous mirtazapine or its pharmaceutically acceptable salts suitable for oral administration. The present invention also relates to a process for the preparation of pharmaceutical compositions of mirtazapine or its pharmaceutically acceptable salts.

al Application No PCT/IB2004/003872

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/20 A61K9/28

A61K31/55

A61P25/20

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEÄRCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7  $\,$  A61K  $\,$  A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Χ .	WO 01/26621 A (AKZO NOBEL N.V; DE NIJS, HENRIK) 19 April 2001 (2001-04-19) example 1	1,3, 7-15,21 1,3, 7-15,21
Y	REMERON - PATIENT PACKAGE INSERT: 'Online! 1994, XP002329207 Retrieved from the Internet: URL:http://www.fda.gov/medwatch/SAFETY/200 4/jun_PI/RemeronTabs_PI.pdf> 'retrieved on 2005-05-24! * DESCRIPTION *	1,2,6, 16-20 1,2,6, 16-20
Y	EP 1 209 159 A (SUMIKA FINE CHEMICALS CO., LTD; SUMITOMO CHEMICAL COMPANY, LIMITED) 29 May 2002 (2002-05-29) claims	1-21

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents:      A* document defining the general state of the art which is not considered to be of particular relevance      E* earlier document but published on or after the International filing date      L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)      O* document referring to an oral disclosure, use, exhibition or other means      P* document published prior to the international filing date but later than the priority date claimed	<ul> <li>"T" later document published after the International filling date or priority date and not in conflict with the application but died to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search  24 May 2005	Date of mailing of the International search report  09/06/2005
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL - 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  Fax: (+31-70) 340-3016	Authorized officer  Minas, S

Intern lal Application No PCT/IB2004/003872

	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Υ	EP 1 225 174 A (SUMIKA FINE CHEMICALS CO., LTD) 24 July 2002 (2002-07-24) page 5, paragraph 33; claims; examples	1-21
<b>X</b>	EP 0 436 252 A (AKZO N.V) 10 July 1991 (1991-07-10) claims; example 2	1
X	WO 01/58453 A (AKZO NOBEL N.V; RUIGT, GERARDUS, STEPHANUS, FRANCISCUS; VAN DEN BERG,) 16 August 2001 (2001-08-16) examples	1
	·	
		:
		·

Intern ial Application No PCT/IB2004/003872

Patent document cited in search report		Publication - date		Patent family member(s)	Publication date
WO 0126621	A	19-04-2001	ATU AU BRA CN CZE DE DO DE SK HU PK NOZ PK TA	274899 T	15-09-2004 17-03-2005 23-04-2001 11-06-2002 19-04-2001 C 06-11-2002 17-07-2002 18-09-2003 07-10-2004 20-01-2005 19-04-2001 24-07-2002 01-12-2003 08-04-2005 28-01-2003 25-03-2003 20-08-2002 30-05-2002 26-03-2004 10-09-2002 23-09-2002 20-06-2003
EP 1209159	A	29-05-2002	AT AU CA DE EP JP SI US	282616 T 4030101 A 2346195 A1 60107189 D1 1209159 A2 2002220390 A 1209159 T1 2002065413 A1	15-12-2004 06-06-2002 27-05-2002 23-12-2004 29-05-2002 09-08-2002 30-04-2005 30-05-2002
EP 1225174	A .	24-07-2002	AT AU CA DE DK EP AU ES WO PT US	261966 T 763502 B2 7447100 A 2370376 A1 60009117 D1 60009117 T2 1225174 T3 1225174 A1 6019900 A 2214318 T3 0138329 A1 0138330 A1 1225174 T 2002103372 A1 2003130504 A1 2004138447 A1	15-04-2004 24-07-2003 04-06-2001 31-05-2001 22-04-2004 21-10-2004 05-07-2004 24-07-2002 04-06-2001 16-09-2004 31-05-2001 31-05-2001 31-05-2004 01-08-2002 10-07-2003 15-07-2004
EP 0436252	A	 10-07-1991	AT AU AU CA DE DE DK EP	93136 T 634614 B2 6839890 A 2033418 A1 69002822 D1 69002822 T2 436252 T3 0436252 A1	04-07-1991 01-07-1991 23-09-1993 23-12-1993

Intern al Application No
PCT/IB2004/003872

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0436252	Α		ES	2060001 T3	16-11-1994
2. 0.00202			ΙE	904531 A1	03-07-1991
			JР	3051459 B2	12-06-2000
			JP	4210638 A	31-07-1992
			KR	156735 B1	16-11-1998
			NZ	236626 A	28-10-1992
			PT	96401 A ,B	15-10-1991
			US	5238688 A	24-08-1993
			ZA	9010452 A	30-10-1991
WO 0158453		16-08-2001	AU	780439 B2	24-03-2005
			AU	3024701 A	20-08-2001
			BR	0108261 A	05-03-2003
			CA	2396209 A1	16-08-2001
			CN	1395487 A	05-02-2003
	•		CZ	20022330 A3	13-11-2002
			WO	0158453 A1	16-08-2001
			ΕP	1257278 A1	20-11-2002
			HU	0204391 A2	28-05-2003
			JP	2003522147 T	22-07-2003
	•		NO	20023803 A	09-10-2002
			PL	356721 A1	28-06-2004
			SK	11442002 A3	04-02-2003
			US	2003022888 A1	30-01-2003
			ZΑ	200205238 A	29-09-2003